REMARKS

Claims 1-49 are pending. Claims 1-7, 33, 37-43 and 45-49 stand rejected under 35 U.S.C. §§ 112 and 102. Claims 35-36 and 44 are objected to. Applicant acknowledges with appreciation the Examiner's indication that claims 8-10, 18, 20, 34-36 and 44 would be allowable if rewritten in independent form.

By amendment herein, the typographical error in claim 1 has been corrected. Furthermore, claim 27 has been amended to clarify that the device is formed and deployed in the same three-dimensional shape, as described for example on page 6, lines 19-23. Thus, claim 27 has been amended solely to make explicit what was originally implicit. In addition, the specification has been amended to correct a typographical error on page 5 and to revise the Abstract. Finally, new FIG. 4 and a description thereof has been added as requested by the Examiner. Entry of the foregoing amendments is requested.

In view of the foregoing amendments and following remarks, Applicant respectfully requests reconsideration of the claims.

Abstract

Pursuant to the Examiner's request the Abstract has been amended herein to provide a more specific description of the structure.

Informalities

Applicant thanks the Examiner for noting the typographical error on page 5 and have corrected the error by amendment herein.

Drawings

Applicant submits herewith new FIG. 4 to show, as requested by the Examiner, injection-molded elements of various shapes; linkage of the elements and a detachable pusher assembly. Although Applicant submits that the original drawings and specification adequately showed and described these features, the new drawing is submitted to expedite prosecution. The specification has also been amended to describe the new Figure.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-26 were rejected under 112, second paragraph as allegedly indefinite. (Office Action, page 2). In particular, the recitation in claim 1 of "the three-dimensional configuration" was alleged to lack antecedent basis. Applicant has corrected the unintended error by amendment herein, thereby obviating this rejection.

Rejections Under 35 U.S.C. § 102

Claims 1-7, 12-17, 22-33, 38-43, 45, 46 and 48 stand rejected as allegedly anticipated by U.S. Patent No. 5,925,059 (hereinafter "Palermo"). Claims 1-3, 24, 26-30, 47 and 48 stand rejected as allegedly anticipated by U.S. Patent No. 5,309,367 (hereinafter "Boock") and claims 1, 2, 4, 5, 11, 19, 21, 24-27, 30, 31, 37, 48 and 49 stand rejected as allegedly anticipated by U.S. Patent No. 6,261,305 (hereinafter "Marotta").

Because none of the references describe or demonstrate the claimed methods and devices, Applicant traverses the rejections and supporting remarks.

Palermo, Boock and Marotta are all silent as to making vaso-occlusive devices using injection-molding procedures as recited in pending claims 1-26. Indeed, prior to the present disclosure, implantable devices were typically made by winding materials around mandrels, as described in detail in Palermo. Simply put, there is absolutely no disclosure in Palermo, Boock or Marotta regarding methods that involve injection molding to make elements of their devices. Accordingly, method claims 1-26 cannot be anticipated by these references.

Similarly, none of the references describe, demonstrate of suggest vaso-occlusive devices that are formed into a three-dimensional configuration and deployed in that same three-dimensional configuration, as recited in claims 27-49. In start contrast to the claimed devices, the Palermo, Marotta and Boock references disclose devices that deform substantially after deployment into a body cavity. (See, *e.g.*, Palermo describing at col. 8, lines 35-38 how "the coil assembly show assumes a second diameter when ejected from the tip of the catheter..."; Boock describing devices which include both an "elastic" portion and an "expandable ring" portion"; and the Abstract of Marotta describing a "leaf portion capable of being urged against and blocking the opening of the aneurysm thereby leading to obliteration of the aneurysm.") In other words, none of the cited references describe or demonstrate devices as claimed.

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In sum, the pending claims are not anticipated by any of the cited references and withdrawal of the rejections is respectfully requested.

CONCLUSION

For the reasons discussed above, Applicant submits that the claims are in condition for allowance and request early notification to that effect. If the Examiner has any further issues or wishes to discuss any of the foregoing, she is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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Date: 14 Jan 03

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VERSION SHOWING CHANGES MADE

In the specification:

The following paragraph has been added on page 5, line 20:

--FIG. 4 depicts an exemplary device **200** having a series of shaped elements. Exemplary shapes depicted in the drawing include ovoid **210**, spherical **215**, conical **220**, and pyramidal **230** elements. The series of shaped elements are linked **240** and are detachably connected to a pusher elements **250**.--

The paragraph beginning on line 22 of page 5 has been amended as follows:

--Occlusive (*e.g.,* embolic) compositions are described. The compositions described herein find use in vascular and neurovascular indications and are particularly useful in treating aneurysms, for example small-diameter, curved or otherwise difficult to access vasculature, for example cerebral aneurysms. Methods of making and using these vaso-occlusive elements also form [an] aspects of this invention. The compositions and methods described herein are particularly useful when the element is comprised primarily or entirely of polymeric material, for example, absorbable polymeric material.--

The Abstract has been amended as follows:

--Compositions comprising injection-molded vaso-occlusive elements are described. Thus, one or more injection-molded elements are formed into a desired three-dimensional configuration. Each injection-molded element of the device may have a different shape, for example, ovoid, spherical, cylindral or pyramidal. The devices described herein may also be detachable linked to pusher element for placement in a body cavity. Also described are methods of making and using these elements.--

In the claims:

1. (Amended) A method for producing a vaso-occlusive element comprising the step of injection molding a polymeric material into a [the] three-dimensional configuration.

27. (Amended) A vaso-occlusive device comprising at least one polymeric material, wherein said device is formed into a three-dimensional configuration and is deployed [in a] into a body cavity in the three-dimensional configuration.

PENDING CLAIMS

1. (Amended) A method for producing a vaso-occlusive element comprising the step of injection molding a polymeric material into a three-dimensional configuration.

2. The method of claim 1, wherein the polymeric material is absorbable.

3. The method of claim 2, wherein the absorbable material is selected from the group consisting of polyglycolide, poly-L-lactide, poly(g-ethyl glutamates, polyphosphazene, polysaccharides, polyorthoesters, polycaprolactone, polyhydroxybutyrate, polydioxanone, polycarbonates, polyanhydrides, copolymers or blends thereof, collagen, elastin, fibrinogen, fibronectin, vitronectin, laminin, gelatin and combinations thereof.

4. The method of claim 1, wherein the three-dimensional configuration comprises a cylindrical configuration having a longitudinal axis.

5. The method of claim 4, wherein the cylindrical configuration further includes a plurality of channels therein.

6. The method of claim 5, wherein the channels are perpendicular to the longitudinal axis of the device.

7. The method of claim 1, wherein the three-dimensional configuration comprises a plurality of shaped structures linked in series.

8. The method of claim 7, wherein the shaped elements are ovoid.

9. The method of claim 7, wherein the shaped elements are spherical.

10. The method of claim 7, wherein the shaped elements are conical or pyramidal.

11. The method of claim 7, wherein the three-dimensional configuration is a single-molded element.

12. The method of claim 7, wherein the three-dimensional configuration is formed from two or more separate elements.

13. The method of claim 7, wherein the linking elements comprise a polymeric wire or a ductile metallic wire.

14. The method of claim 1, further comprising the step of providing one or more severable junctions detachably connected to a pusher element.

15. The method of claim 14, wherein the severable junction comprises an electrolytically detachable assembly adapted to detach by imposition of a current on said pusher element.

16. The method of claim 14, wherein the severable junction comprises a mechanically detachable assembly adapted to detach by movement or pressure imposed on or within said pusher element.

17. The method of claim 14, wherein the severable junction comprises a thermally detachable assembly adapted to detach by localized delivery of heat to said junction.

18. The method of claim 14, wherein the severable junction comprises a radiation detachable assembly adapted to detach by delivery of electromagnetic radiation to said junction.

19. The method of claim 1, further comprising micro-machining the injection-molded element.

20. The method of claim 1, further comprising chemically etching the injection-molded element.

21. The method of claim 1, further comprising laser cutting the injection-molded element.

22. The method of claim 1, further comprising linking a plurality of the injection-molded elements.

23. The method of claim 22, wherein the linking is by a method selected from the group consisting of soldering, interference fitting, friction fitting, stringing, ultrasonic welding, thermal welding and solvent bonding.

24. The method of claim 1, further comprising the step of blending one or more radio-opaque materials with the polymer.

25. The method of claim 1, wherein the injection molding comprises insert molding a metallic wire within the three-dimensional configuration.

26. A vaso-occlusive device produced by the method of claim 1.

27. (Amended) A vaso-occlusive device comprising at least one polymeric material, wherein said device is formed into a three-dimensional configuration and is deployed into a body cavity in the three-dimensional configuration.

28. The vaso-occlusive device of claim 27, wherein the vaso-occlusive device comprises at least one absorbable or biodegradable polymer.

29. The device of claim 28, wherein the absorbable material is selected from the group consisting of polyglycolide, poly-L-lactide, poly(g-ethyl glutamates, polyphosphazene, polysaccharides, polyorthoesters, polycaprolactone, polyhydroxybutyrate, polydioxanone, polycarbonates, polyanhydrides, copolymers or blends thereof, collagen, elastin, fibrinogen, fibronectin, vitronectin, laminin, gelatin and combinations thereof..

30. The device of claim 27, wherein the three-dimensional configuration comprises a cylindrical configuration having a longitudinal axis.

31. The device of claim 30, wherein the cylindrical configuration further includes a plurality of channels therein.

32. The device of claim 31, wherein the channels are perpendicular to the longitudinal axis of the device.

33. The device of claim 27, wherein the three-dimensional configuration comprises a plurality of shaped structures linked in series.

34. The device of claim 33, wherein the shaped elements are ovoid.

35. The device of claim 33, wherein the shaped elements are spherical.

36. The device of claim 33, wherein the shaped elements are conical or pyramidal.

37. The device of claim 33, wherein the three-dimensional configuration is a single-molded element.

38. The device of claim 33, wherein the three-dimensional configuration is formed from two or more separate elements.

39. The device of claim 33, wherein the linking elements comprise a polymeric wire or a ductile metallic wire.

40. The device of claim 27, further comprising the step of providing severable junction detachably connected to a pusher element.

41. The device of claim 40, wherein the severable junction comprises an electrolytically detachable assembly adapted to detach by imposition of a current on said pusher element.

42. The device of claim 40, wherein the severable junction comprises a mechanically detachable assembly adapted to detach by movement or pressure imposed on or within said pusher element.

43. The device of claim 40, wherein the severable junction comprises a thermally detachable assembly adapted to detach by localized delivery of heat to said junction.

44. The device of claim 40, wherein the severable junction comprises a radiation detachable assembly adapted to detach by delivery of electromagnetic radiation to said junction.

45. The device of claim 27, further comprising a radio-opaque material.

46. The device of claim 45, where the radio-opaque material is selected from the group consisting of tantalum, tantalum oxide, tungsten, bismuth oxide, barium sulfate, platinum, and gold.

47. The device of claim 27, further comprising a bioactive material.

48. The device of claim 27, produced by injection molding.

49. The device of claim 48, wherein the device is micro-machined.

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